



**THE SIDNEY KIMMEL**  
COMPREHENSIVE CANCER CENTER  
**AT JOHNS HOPKINS**

**Graft Engineering Laboratory and  
Cell Processing and Gene Therapy Facilities  
The Harry and Jeanette Weinberg Building  
401 North Broadway / Room 2450  
Baltimore, MD 21231-2410  
(410) 502-1019**

October 26, 2004

Division of Dockets Management  
HFA-305  
Food and Drug Administration  
5630 Fishers Lane Rm 1061  
Rockville, MD 20852

Re: Docket No. 2004N-0408  
Regulatory Site Visit Training Program

Dear Sir/Madam,

We are writing to express our interest in participating in the Regulatory Site Training Program for CBER staff. Our program offers training experiences in several areas of cellular therapy and vaccine production. Our Graft Engineering Laboratory performs routine cell processing for bone marrow and stem cell transplantation in both the allogeneic and autologous setting. Procedures include product receipt, concentration and cryopreservation, mononuclear cell preparation by density gradient separation and apheresis machines, CD34 selection, and patient infusion procedures including cord blood washing for transplants. We also perform other procedures under IND. Our Cell Processing and Gene Therapy Facility is a class 10,000 cGMP facility with 4 suites specializing in the production of cell-based cancer vaccines. This includes both master and working cell banks and clinical lot production. All aspects of clinical production are under the auspices of quality assurance oversight, which includes an in-house environmental monitoring program and independent review of GLP release testing results. All products prepared are for phase I/II clinical trials for oncology patients at our institution. Finally, we offer the unique experience in the translational development laboratory. Our development lab performs process optimization for both facilities. This includes optimization of culture conditions (media evaluation, cell concentration, container evaluation), stability studies, growth arrest studies and contribution to the Chemistry, Manufacturing and Controls section of IND submissions.

As a leading academic medical center, we regularly train others in the industry and strongly support this initiative by CBER. We would be happy to customize a training experience for your staff to meet specific needs. We appreciate your consideration and look forward to a possible collaboration in this endeavor.

Sincerely,

Kathy Loper MHS, MT(ASCP)  
Manager, GEL and CPGTF